IN THE UNITED STATES
PATENT AND TRADEMARK OFFICE

Applicant: Carter, *et al.*

Serial No.: 09/924,110

Filed: August 7, 2001

For: "MATERIALS AND METHODS FOR IMPROVED BONE TENDON BONE TRANSPLANTATION"

Group Art Unit: 3738

Examiner: Alvin J. Stewart

CERTIFICATE OF EXPRESS MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as Express Mail in an envelope addressed to: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this:

March 28, 2005

Donald J. Pochopien
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DECLARATION UNDER 37 C.F.R. § 1.132 OF RAYMOND E OLSEN

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I Raymond E. Olsen, M.S. declare as follows:

1. A true and correct copy of my curriculum vitae is attached hereto as Exhibit A.

2. I received a B.S. degree in Biology with a minor in chemistry from Southern Utah University in June of 1987. After graduation, I became the Section Manager of Acute Toxicology and Special Projects at Utah Biomedical Test Laboratory, Salt Lake City, Utah and held that position between 1987 and 1988. Thereafter, I became employed at E.M. Goble Research, Inc. in Logan Utah, as Director of Research (1988-1989), and as Vice President (1989-1996). See Exhibit A

3. I received my M.S. degree in Bioveterinary Sciences in June of 1992 from Utah State University in Logan Utah. My thesis was directed to the analysis of prosthetic anterior cruciate ligament repair in sheep. See Exhibit A.

4. In 1996, I was a founder of Frontier BioMedical, Inc., Logan Utah and held the position of President and CEO until 2002. In 2002, I became the Chairman of Frontier BioMedical, Inc. and have held that position ever since. See Exhibit A at page 1.

5. Frontier BioMedical is a laboratory engaged in providing the biomedical industry with animal testing of its proposed implants to determine the feasibility of using the implants or their modes of attachment in humans for treating congenital or acute medical conditions that can be remedied by the use of such implants. A significant part of Frontier's business involves the testing of bone tendon bone implants (BTBs) such as for anterior cruciate ligament repair.

6. I personally have extensive experience in the use of BTBs and interference screws. I also have multiple publications and have made numerous presentations on ACL ligament repair and the use of interference screws. I also am a co-inventor on the five following U.S. Patents: U.S. Pat. 5,393,302, entitled "Process for Endosteal Ligament Mounting," which issued 02/28/95; U.S. Pat. 5,266,075, entitled Tendon Threader For Endosteal Ligament Mounting," which issued 11/30/93; U.S. Pat. 6,306,138, entitled "ACL Fixation Pin and Method," which issued 10/23/01; U.S. Pat. 6,558,389, entitled "Endosteal Tibial Ligament Fixation with Adjustable Tensioning," which issued 05/06/03; and U.S. Pat. 6,780,188, entitled "ACL Fixation Pin," which issued August 24, 2004. See Exhibit A at pages 2-3.

7. Based upon my education and experience, I consider myself to be a person of ordinary skill in the art of BTB structure, testing and modes of implantation.

8. I have reviewed the specification of the above identified patent application, the rejected claims, the Official Action of 09/28/04 and the cited art. I understand their contents. Specifically, I understand that the Patent Office has rejected claims 1, 2, 4, 8, 9, and 31-40 under 35 U.S.C. §103(a) for being allegedly unpatentable over U.S. Pat. 5,067,962 ("Campbell") in view U.S. Pat. 5,961,520 ("Beck"). According to the Patent Office, Campbell discloses a "xenograft replacement ligament comprising a bone-ligament-bone attachment with a naturally occurring [ligament to bone] attachment (see abstract and Fig. 3)" and that "Figure 3 discloses bone blocks shaped into a dowel." [Official Action at page 2.] The Patent Office acknowledges that "Campbell et al does not disclose a groove along the length of each bone block." [Official Action at page 2.] The Patent Office then cites to Beck and states that Beck "discloses an artificial ligament comprising an anchoring system made of bone (see col. 6, lines 36-39) and having a groove along the length (see Fig. 2, see element 17) for the purpose of inserting an attachment screw and attach the attachment system to the patient's bone." [Official Action at page 2.] The Patent Office goes on to conclude that "[i]t would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the bone blocks of the Campbell et al reference with **the longitudinal groove (see surface 17) of the Beck, Jr. et al. reference**, in order to insert an attachment screw and attach the attachment system to the patient's bone." [Official Action at pages 2-3 (bridging sentence).] I disagree.

9. At the time of Beck, and the filing date of the present application, there were two techniques for performing anterior cruciate ligament repair. The original and oldest technique required an "**open**" knee wherein the bottom plate of the femur and the top plate of the tibia were partially disarticulated from one another to reveal their opposing inner surfaces. To practice the art as described by Campbell the physician would drill a hole a predetermined distance into the opposing plates of the femur and the tibia. Thereafter, he would insert a bone plug shaped for each hole as disclosed in Campbell. Campbell's bioprosthetic ligament can only

be implanted using this open technique. Because of the extensive trauma to the knee imposed by this technique, a long recovery time was required.

A second and less invasive technique is the **endosteal** technique. See my U.S. Pats. 5,393,302; 5,266,075 and 6,558,389. This technique leaves the knee joint intact and uses an endoscope to visualize the coarse of a drilled hole up through the tibia into the femur. See Exhibit B: U.S. Pat. 5,393,302 at FIG. 6 at element 34 ("femoral tunnel section") and Exhibit C: U.S. Pat. 6,306,168 at FIGs 10 and 11 at element 10 ("femoral tunnel"). A BTB having a diameter slightly less than the femoral bone tunnel is then slid into the tunnel, positioned, tensioned and then fixed.

10 Upon reviewing U.S. Pat. 5,067,962 ("Campbell") as a person skilled in the art, it is apparent that Campbell discloses a xenograft BTB comprising a ligament having two opposing ends and a frustoconical-shaped bone block naturally attached to each of the opposing ends the ligament. In the xenograft of Campbell, each frustoconical shaped bone block, which has a large diameter end and a small diameter end, is attached to an opposing end of the ligament via the bone block's wide diameter end. The frustoconical shape of the bone blocks of Campbell reflect that they can only be inserted into a knee that has been "fully **opened**" such that the femur and the opposing tibia are partially disarticulated. With the knee in deep flexion, the bone blocks would be placed in there respective holes. The first bone block of Campbell may be pinned in place immediately after it is inserted in its respective hole or it may be pinned after the insertion of the second bone block in its respective hole. Ultimately, the patella and the lateral ancillary structures of the knee need to be reattached.

11. Upon reviewing U.S. Pat. 5,961,520 ("Beck") as a person of ordinary skill in the art, it is immediately apparent from Beck's title ("Endosteal anchoring device for urging a ligament against a bone surface") that Beck discloses a device for use with the endosteal technique which requires a bone tunnel drilled through the tibia and into the femur as shown in U.S. Pat. 6,306,168 at FIGs. 10 and 11 at element

10 ("femoral tunnel"). In Beck, both the interference screw 28 ("threaded insertion member") and the BTB 16 ("anchor body") are inserted up through the bone tunnel in the tibia (not shown) and into the femoral bone tunnel 12 shown in FIGs 1, 3, and 5-6 of Beck. The end of the BTB 16 of Beck is fixed in place by interference screw 28 ("threaded insertion member") which in turn is turned by tool 33 in FIG. 2 of Beck. Tool 33 of Beck is a linear tool that is inserted into the bone tunnel and up to the anchor body where it can be directly twisted to drive the interference screw 28 ("threaded insertion member").

12. One skilled in the art would have no reason or motivation to put a groove on the bone block of Campbell. Consistent with its title, Beck goes into great detail to state that its methodology and devices are directed for use with the endosteal procedure. [See Beck at col. 2, lines and at col. 4, lines 45.] In contrast, Campbell never even mentions the endosteal or laparoscopic techniques. That is because it would have been obvious to one skilled in the art at the time of the Applicants' invention that a large incision and an **open** knee is required for implantation of the BTB of Campbell.

13. I will assume for the sake of argument that one added the grooves of Beck to the BTB of Campbell. A first screw could be inserted to fix one bone block of the BTB of Campbell to the corresponding hole in the femur because the joint is open and accessible to a screw and a driver for inserting the screw. However, when the second bone block is fixed in the corresponding hole in the tibia, it is desirable for the sake of proper tensioning and isometry that the joint be in a shallow degree of flexion thus closing access to the second bone block. Neither Beck nor Campbell teaches how to insert the second screw in a closed joint. This is why Campbell used stainless steel pin 32 in hole 26 that traversed the tibia and the bone block. See Campbell at FIG. 4 and at col. 4, lines 38-40 ("There, it is attached to the tibia28 by suitable means such as a second stainless steel pin 32 through hole 26."). Thus, the combination of Campbell over Beck would not motivate one skilled in the art to put a groove in each of the bone blocks of Campbell's BTB

because the combination of Campbell and Beck (even if combinable) does not disclose how to use or install such a graft. Clearly, one skilled in the art would have no motivation to make a BTB that could not be installed, or that would require techniques neither taught nor suggested in Campbell or Beck. However, more importantly, Campbell and Beck are disclosing BTBs for use in very different techniques. Hence, it is my opinion and conclusion, as a person skilled in the art, that it would not have been obvious to take the groove feature of Beck and add them to the bone blocks of Campbell to create an invention that neither teaches how to use.

14. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. § 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Respectfully submitted,

By 
Raymond E. Olsen, M.S.

Dated: March 25, 2005

CURRICULUM VITAE

PERSONAL:

Raymond E. Olsen
791 Canyon Terrace
Smithfield, Utah 84335

Telephone: (435) 563-3252
Birth date: 22 February 1955

EDUCATION:

Utah State University, Logan, Utah, June 1992
Master of Science, Bioveterinary Sciences

Southern Utah University, Cedar City, Utah, June 1987. Bachelor of Science, Major: Biology and Agriculture, Minor: Chemistry

PROFESSIONAL EXPERIENCE:

Founder and Chairman, Frontier BioMedical, Inc. Logan, Utah, 2002-Present

President & CEO, Frontier BioMedical, Inc. Logan, Utah, 1996-2002

Vice President, Goble Research, Inc. Logan, Utah, 1989-1996.

Director of Research, E. M. Goble Research, Logan, Utah, 1988-1989.

Section Manager of Acute Toxicology and Special Projects, Utah Biomedical Test Laboratory, Salt Lake City, Utah, 1987-1988.

RELATED ACTIVITIES:

Member Orthopaedic Research Society 2001- Present

Member Society for Biomaterials 2000- Present

Past President, Logan Kiwanis Club 1997-1998.

Board Member, Logan Kiwanis Club 1993-1999.

Member American Association for Laboratory Animal Science 1987 - present

Teaching Assistant, Animal Science and Reproductive Physiology, Southern Utah University 1985 - 1987.

Advisor/Coach, Rodeo Team, Southern Utah University 1986 - 1987.

President, Southern Utah University Agriculture Club 1984 - 1986.

Director of Student Relations, Associated Students of Southern Utah University Executive Council 1984 - 1985.

PUBLICATIONS:

1. Ron Clark, M.D., Raymond E. Olsen, M.S., Brad J. Larson, M.D., E. Marlowe Goble, M.D., and Rhett P. Farrer, P.T.: Cross Pin Femoral Fixation: A New Technique for Hamstring ACL Reconstruction of the Knee, *The Journal of Arthroscopic and Related Surgery,* Vol. 14, No.3, April 1998: pp 258-267.

2. Goble, E.M., Kane, S.M., Wilcox, T.R., Olsen, R.E. (1996) Advanced Arthroscopic Instrumentation, Operative Arthroscopy, Second Edition, Chapter 2: 7-12.

3. The Development Of Suture Anchors For Use In Soft Tissue Fixation To Bone. *American Journal of Sports Medicine*, 1994. Vol 22. Pages 236-239.

4. Olsen, R.E: A Six- and Twelve-Month Evaluation of the Safety and Efficacy of the Leeds-Keio Prosthetic Anterior Cruciate Ligament in Sheep. Master Thesis, Utah State University, 1993.

RESEARCH & PRESENTATIONS:

1. Histopathological and Biomechanical Analysis of Biocleanse Treated Bone Xenograft vs. Biocleanse Treated Gamma Irradiated Bone Xenograft vs. Untreated Bone Xenograft vs. Untreated Bone Allograft in the Sheep Model. Society for Biomaterials Meeting. May 2003.

2. Biological Incorporation of Cortical Bone Interference Screws. Metcalf Memorial Seminars in Arthroscopy and Reconstructive Surgery. January 2001.

3. Hamstring ACL Reconstruction with Endosteal Cross Pin Femoral Fixation. The American Orthopedic Society For Sports Medicine. August 1996.

4. Advanced Arthroscopic Instrumentation. Metcalf Memorial Seminars in Arthroscopy. January 1995.

5. A double-blind comparison of the efficacy and safety extended outpatient treatment with subcutaneous Normiflo versus Placebo for the prevention of venous thromboembolism in patients after hip or knee replacement surgery. September 1993.

6. A double-blind dose-ranging comparison of the safety and efficacy of subcutaneous Normiflo versus Warfarin for the prevention of deep-vein thrombosis in patients undergoing knee replacement surgery. August 1992.

7. A Comparison of the efficacy and safety of subcutaneous RD Heparin versus Oral Warfarin for prevention of deep-vein thrombosis in patients undergoing unilateral elective knee or hip replacement surgery. April 1990.

PATENTS HELD:

1. "Process for Endosteal Ligament Mounting" February 28, 1995.
   Patent Number: 5,393,302

2. "Tendon Threader For Endosteal Ligament Mounting" November 30, 1993.
   Patent Number: 5,266,075

3. "ACL Fixation Pin and Method" October 23, 2001
   Patent Number: 6,306,138

4. "Endosteal Tibial ligament Fixation with Adjustable Tensioning" May 6, 2003
   Patent Number: 6,558,389

5. "ACL Fixation Pin" August 24, 2004 Patent Number: 6,780,188

PATENT APPLICATIONS:

1. 20040158244 Endosteal tibial ligament fixation with adjustable tensioning:

2. 20040073194 Catheter assemblies for controlled movement of fluid:

3. 20020087160 Method and implant for securing ligament replacement into the knee:

4. 20020065528 Endosteal tibial ligament fixation with adjustable tensioning:

5. 20020058941 ACL fixation pin :

UNPUBLISHED MANUSCRIPTS:

1. A Twelve Month Chronic Safety Evaluation of a Prosthetic Anterior Cruciate Ligament in Sheep.

2. A Comparative Study of Fixation Strengths in Kurosaka Screws, Cross pins, Screw & Washer Fixation and Set Screw.

3. A Comparative Study of Initial Fixation Strengths of the Kurosaka Bone Screw and the Arthrex Interference Screw.

4. Comparative Cyclic Testing of the 9 x 25 Millimeter Set Screw and the 9 x 25 Millimeter M. Kurosaka™ Interference Screw.

5. Initial Fixation Strength Testing of Biomet 9 X 30 Millimeter And 7 X 30 Millimeter Interference Screws.

6. A Comparative Study of Initial Fixation Strengths of the DePuy 9mm Polished Endoscopic Fixation Screw and the DePuy 7mm Polished Endoscopic Fixation Screw.

7. A Radiographic, Biomechanical, and Histological Study of Time to Biological Fixation.

8. Fatigue Testing for 9X30mm Interference Screws and 9x30 Set Screws in Peg Femur.

9. Initial Fixation Strengths of the Kurosaka Advantage Fixation Screws When Placed Into a Pre-Tapped Bone Tunnel and Into a Non-Tapped Bone Tunnel.

10. Minimum Distance Site Specific Pull Out Strength Comparison of DePuy DuPont Hylamer-M 3.5 Suture Anchors and DePuy DuPont Absorbable 3.5 Suture Anchors.

11. Comparative Pull Out Strength Analysis of DePuy DuPont Hylamer-M 3.5; DePuy DuPont PLLA 3.5; and Zimmer Statak 3.5 Suture Anchors for Bankart and Rotator Cuff Repair.

12. A Comparative Evaluation of the Tensile Strengths of the Zimmer Statak™ and the Mitek Threaded Anchor.

13. Comparative Dimensional Tolerance of the Mitek 5.0 Threaded Anchor at a Low End Dimension of 0.046" and at a High End Dimension of 0.054".

14. Comparative Evaluation of the Tensile Strengths of the Zimmer Statak and the Mitek Threaded Anchor.

15. Comparative Immediate Fixation Strengths of the 5.0 mm Statak™, 4.0 mm Revo™, 7.4 mm Ogden™, 5.0 mm PeBA™, 3.5 mm ROC™, 5.0 mm Mitek Threaded Anchor, and Mitek Super Anchor™.

16. Tensile Testing of the Initial Fixation Strength of the Gamma Sterilized 7 x 25 mm Hylac™ Absorbable Kurosaka Screw.

17. Tensile Testing of the Initial Fixation Strength of the Alternate Sterilized 7 x 25 mm Hylac™ Absorbable Kurosaka Screw.

18. Tensile Testing of the Initial Fixation Stength of the Alternate Sterilized 7x25mm Hylac Absorbable Kurosaka Screw.

19. Comparative Cyclic Testing of the 9x25mm Set Screw and the 9x25mm Kurosaka Interference Screw.

20. Initial Fixation Strength of the 6x15mm Medicine Lodge Interference Screw and the 7x25mm Medicine Lodge Interference Screw.

21. Rotational Torque Testing of Medicine Lodge Interference Screws and Drivers.

22. Comparative Pull-Out Strengths of the DePuy Hylamer-M Suture Anchor and the 3.5mm Statak in Human Cadaver Specimens.

23. Chemical Delivery Device.

24. Site Specific Tensile Testing of Suture Anchors in Human Cadaver Shoulders.

25. Comparative Pull-Out Strength Analysis of DePuy DuPont Hylamer-M 3.5; DePuy DuPont, PLLA 3.5; and Zimmer, Statak 3.5 Suture Anchors for Bankart and Rotator Cuff Repair.

26. Initial Fixation Strength Testing of 7x20mm Interference Screws in Pig Femur Using Bone Patellar Tendon Graft.

27. Initial Fixation Strength of the 4x12mm Acufex Endobutton.

28. Initial Fixation Strength Testing of 7x20mm Injection Molded PLLA Bioabsorbable Interference Screw in Pig Femur Using Bone Patellar Tendon Graft.

29. Initial Fixation Stength of the 4x12mm Acufex Endobutton in Static Bone Patellar Tendon Tensile Testing.

30. Initial Fixation Strength of the Medicine Lodge Snap-In Device (No. 420009) In Static Bone Patellar Tendon Tensile Testing.

31. Initial Fixation Strength of the Mitek Ligament Anchor in Static Bone Patellar Tendon Tensile Testing.

32. Initial Fixation Strength of the MLI 9 Millimeter Endosteal Fixation Device Using Single Looped Suture.

33. Initial Fixation Strength of the MLI 9 Millimeter Endosteal Fixation Device Using Double Looped Suture.

34. Initial Fixation Strength Testing of 7 x 20 mm Linvatec BioScrew in Pig Femur Using Bone Patellar Tendon Graft.

35. Comparative Pull-Out Strengths of the 3.5 mm DePuy DuPont Orthopaedics™ Hylac™ Cortical Suture Anchor, the 3.5 mm DePuy DuPont Orthopaedics™ Hylac™ Cancellous Suture Anchor and the Zimmer 3.5 mm Statak™ In Human Cadaveric Specimens.

36. Initial Fixation Strength of the 4 x 12 Millimeter Acufex Endobutton In Static Bone Patellar Tendon Tensile Testing.

37. Initial Fixation Strength of the MLI-Endoscopic Cruciate Snap-In Endosteal Fixation Device with Clip-Plate in Static Bone Patellar Tendon Tensile Testing in Porcine Bone Model.

38. Initial Fixation Strength of the MLI-Set Screw in Static Bone Patellar Tendon Tensile Testing in Porcine Bone Model Using an Untapped Six Millimeter Hole for Screw Insertion.

39. Initial Fixation Strength Testing of the MLI-Endoscopic Cruciate Endosteal Fixation Device (Autolock) with 19 x 7 x 0.0018", 0.027" CoCr Cable in Porcine Femur.

40. Initial Fixation Strength of the DePuy Set Screw in Static Bone Patellar Tendon Tensile Testing in Porcine Bone Model Using an Untapped Seven Millimeter Hole for Screw Insertion.

41. Comparative Pull-Out Strengths of the DePuy DuPont Orthopaedics™ 4.5 mm Hylac™ Molded Bone Suture Anchor, the DePuy DuPont Orthopaedics™ 4.5 mm Hylac™

Machined Bone Suture Anchor and the Zimmer 5.0 mm Statak™ In Human Cadaveric Specimens.

42. A Comparative Analysis of Static Tensile Strength, Insertion Torque and Bone Plug Compression of Reabsorbable Set Screws Inserted Using Three Different Sized Taps and a Titanium Set Screw Control.

43. Initial Fixation Strength Testing of the Titanium Cross Pin.

44. Initial Fixation Strength of the MLI-Endoscopic Cruciate Endosteal Fixation Device (Auto-Lock) with 19X7x0.0018", 0.027" CoCr Cable in Porcine Femur.

45. Retrospective Study Investigating Perioperative APG Treatment in Total Knee Patients.

46. Insertion Torque and Initial Fixation Strength of a 0.5 Inch and a 1.0 Inch Radius Nosed Prototype Titanium Set Screw and a Prototype Reabsorbable Set Screw.

47. Cyclically Loaded Fatigue Testing of the Medicine Lodge™ Clip-In Side Plate.

48. Comparative Pull-Out Strengths of the DePuy DuPont Orthopaedics™ 3.5 mm Hylac™ Molded Suture Anchor, the DePuy DuPont Orthopaedics™ 3.5 mm Hylac™ Machined Suture Anchor, and the Zimmer 3.5 mm Statak™ In Human Cadaveric Specimens.

49. Insertion Torque and Initial Fixation Strength of a 0.5" and a 1.0" Radius Nosed Prototype Titanium Set Screw and a Prototype Resorbable Set Screw.

50. Cyclically Loaded Fatigue Testing of the Medicine Lodge™ Clip-In Eyelet.

51. Cyclically Loaded Fatigue Testing of the Medicine Lodge™ Clip-In Side Plate.

52. Cyclically Loaded Fatigue Testing of the Medicine Lodge™ 6 x 15 Millimeter Interference Screw.

53. Cyclically Loaded Fatigue Testing of the Acutex™ Endobutton.

54. Cyclically Loaded Fatigue Testing of the Medicine Lodge Clip-In Side Plate.

55. Analysis of Initial Pull-Out Strengths of the Surgical Dynamics SD Sorb Bioresorbable Suture Anchor in the Human Humeral Head.

59. Fixation Strength of the 4x12mm Acufex Endobutton in a Static Tensile Testing Using a Soft Tissue Graft.

60. Fixation Strength of the Innovasive 8mm Ligament Fastener in Static Tensile Testing.

61. Cyclically Loaded Fatigue Testing of the 8mm Innovasive Devices Ligament Fastener in Foam Block at 37 degrees C.

62. Static Fixation Strength of the Innovasive Soft Tissue Set Screw in a Porcine Bone Model.

63. Initial Fixation Strength Testing of the Innovasive Devices 10mm Clip In Eyelet Device in Porcine Femur.

64. Rotational Torque Testing of Resorbable Interference Screws.

65. Comparative Pull-Out Strengths of Two 3.5 mm (H3, H4) DePuy™ Suture Anchors to the Zimmer 3.5 mm Statak™ and Comparative Pull-Out Strength of Two 4.5 mm (H1, H2) DePuy™ Suture Anchor to the Zimmer 5.0 mm Statak™ in Human Cadaveric Specimens.

66. Static Fixation Strength of the Innovasive Soft Tissue Set Screw in Porcine Bone Model.

67. Static Testing of ACL Fixation Device.

68. Cyclically Loaded Fatigue Testing of the Innovasive Corporation 8mm ACL Clip-In Eyelet.

69. Cyclically Loaded Fatigue Testing of the Innovasive Corporation 8mm Ligament Fastener Device.

70. Cyclically Loaded Fatigue Testing of the Innovasive Corporation 10mm Clip Plate.

71. Static Fixation Strength of the Innovasive Delrin Interference Screw in the Porcine Bone Model.

72. Static Tensile Strength of the Innovasive Devices Soft Tissue Interference Screw in a Porcine Bone Model.

73. Static Fixation Strength of the Innovasive Corporation 6.5x40mm Cross Pin.

74. Static Fixation Strength of the Innovasive Corporation 9x40mm Cross Pin.

75. A 26-Week Safety Evaluation of a Prosthetic Anterior Cruciate Ligament in Sheep.

76. Comparative Pull-Out Strength Analysis of the Initial Fixation Strength of the Surgical Dynamics E-Z TAC and the Mitek G-II In Human Humeral Head.

77. Site Specific Tensile Testing of Suture Anchors In Human Cadaver Shoulders.

78. A Comparative Study of the Innovasive Devices, Inc. Bioabsorbable Meniscal Screw versus the Biofix7 Arrow for Meniscal Repair in the Ovine Model at Six and Twelve weeks Post Surgery.

79. Initial Fixation Strength of the MLI-Endoscopic Cruciate Snap-In Edosteal Fixation Device with Clip-Plate in Static Bone Patellar Tendon Tensile Testing in Porcine Bone Model.

80. Initial Fixation Strength Testing of the MLI-Endoscopic Cruciate Endosteal Fixation Device (Autolock) with 19 x 7 x 0.0018", 0.027" CoCr Cable in Porcine Femur.

81. Evaluation of a New Bone Graft Material and Biomaterial in the Femurs and Tibias of Sheep.

82. A Comparison of the Performance of Bone Source™ Hydroxyapatite Cement Alone and When Combined with a Bone Inductive Agent in the Sheep Metaphysical Defect Model.

83. A Six-Month Chronic Safety Evaluation of a Prosthetic Anterior Cruciate Ligament in Sheep.

84. A 26-week Safety Evaluation of a Prosthetic Anterior Cruciate Ligament in Sheep.

85. A Twelve-Month Chronic Evaluation of Anterior Cruciate Reconstruction Using a Ligament Assisting Device with an Allograft.

86. An 18-Week Evaluation of Anterior Cruciate Reconstruction using a Ligament Assisting Device with an Allograft

87. InVitro Evaluation of Anterior Ligament in Tunnel Fixation Strength.

88. A Six-Month Evaluation of the Ram as an Appropriate Animal Model for the Leeds-Keio Prosthetic Ligament.

89. A BioMechanical and Histological Evaluation of the Biological Ingrowth within the Rolled Fascia Lata Anterior Cruciate Ligament Replacement Allograft.

90. An Evaluation of Cryogenically Preserved Fascia Lata Comparative to Freeze Dried Fascia Lata as a Rolled Allograft for Anterior Cruciate Ligament Replacement. (A Comparative study Conducted Concurrent with study #110)

91. An Evaluation of the Concept Bioreabsorbable Endosteal Fixation Device.

92. A Nine-Week Pilot Evaluation of the Concept Bioreabsorbable Endosteal Fixation Device.

93. A Nine-Week Pilot Evaluation of the Efficacy of the Concept Bioreabsorbable Endosteal Fixation Device.

94. A Comparative Evaluation of the Tensile Strengths of the Zimmer Statak and the Mitek Threaded Anchor.

95. Initial Fixation Strength of the 6mm x 15 mm Medicine Lodge Inference Screw and the 7x25mm mm Medicine Lodge Interference Screw.

96. Initial Fixation Strength Testing of 7 x 20 mm Inference Screw in Pig Femur Using Bone Patellar Tendon Graft.

97. The Effect of Pulsed Electromagnetic Fields on the Quality of Lumbar Vertebral Fusion in the Ovine Model.

98. The Effect of Pulsed Electromagnetic Fields on the Quality of Lumbar Vertebral Fusion in the Ovine Model.

99. Tibial Fixation of a Simulated Hamstring Anterior Cruciate Ligament Allograft in the Ovine Model.

100. Surface Hemiarthroplasty of the Femoral Head Using an Osteoarticular Allograft in the Sheep.

101. Meniscal Repair Using the Surgical Dynamics Bioabsorbable Meniscus Staple Versus the Biofix Arrow in the Ovine Model.

102. RF Energy in Tissues Welding and Hemostasis Application: A Pilot Study.

103. Study of the Effect of Pulsed Electromagnetic Fields on the Quality of Cage-Instrumented Lumbar Vertebral Fusion in the Ovine Model.

104. Endoscopic Multi-Level Discectomy in the Pig Model.

105. Comparative Evaluation of Osteoglass and Bioglass Putty versus OsteoSet in Osseous Cyst Defects in the Long Bones of Goats.

106. A Pilot Study to Histologically Determine the Compatibility of the Human Xenograft.

107. Determination of the Effect of Radiofrequency Energy Delivered on the Porcine Urethral Sphincter and Bladder Neck.

108. Comparative Initial Fixation Strength of the Mitek Cross pin and the Stryker Cross-Screw by Static Fixation Testing in Porcine Femur.

109. A Comparative Healing Study of the Mitek BioComposite Screw and a Mitek Absolute BioInterference Screw for Graft Fixation in ACL Reconstruction in the Ovine Model.

110. Comparative Testing of the HylacTM Absorbable Set Screw Using Two Sterilization Techniques.

111. Comparative Dimensional Tolerance of the Mitek 5.0 Threaded Anchor At A Low End Dimension of 0.046" and At A High End Dimension of 0.054".

112. Final Report For Medicine Lodge, Inc. Chemical Delivery Device.

113. FDA Master File Submission: Static Testing of 9x25 mm and 7x25 mm Interference Screws.

114. Ultra High Molecular Weight Polyethylene Woven Fiber as a Prosthetic Anterior Cruciate Ligament: A Biomechanical and Histological Analysis in Sheep.

115. A Radiographic, Biomechanical and Histological Study of Time to Biological Fixation.

116. Retrospective Two-Year Follow-Up of ACL Reconstruction Using A Fascia Lata Allograft.

117. Insertion Torque and Initial Fixation Strength of a 9 x 30 millimeter Prototype Resorbable Set Screw and a 9 x 30 millimeter Titanium Set Screw Control.

118. Cyclically Loaded Fatigue Testing of the Mitek Ligament Anchor in a Bone Tendon Bone Graft.

119. Static Tensile Strength of Bone Fixation Features.

120. In Vitro Evaluation of Initial Pull Out Strength of the Innovasive Devises Inc. LINX-BT, LINX-HT and HT with Revision Anchor Base.

121. Fixation Qualities of the Innovasive #5 EBS Suture vs #5 Ethibond Suture.

122. Static Fixation Strength of the Innovasive Corporation Small (6.5mm) Cross Pin.

123. Cyclically Loaded Fatigue Testing of the LinX-BT in a Bone Tendon Bone Graft.

124. Comparative Cyclic Fatigue Test of the DePuy Phantom 7x25mm screw, the DePuy Resorbable Soft Tissue Interference Screw Round Head and the DePuy Resorbable Soft Tissue Square Head for fixation of soft tissue to ACL grafts in a bone tunnel.

125. Static Tensile Strength of the Innovasive Soft Tissue Set Screw.

126. Static Fixation Strength of the Richards Small and X-Small Fixation Staple without Spikes.

127. Closure of the Femoral Artery Puncture Site using the Universal Introducer with the Two System Sealant in a Sheep Model.

128. Repair of the Ovine Meniscus using the Arthrex Bioabsorbable Meniscal Repair Device vs. the Bionix Arrow.

129. Comparative Evaluation of the Osteoglass and Bioglass Putty versus OsteoSet for Posterolateral Spinal Fusion and lilac Crest Augmentation.

130. Study of the Articular Cartilage Repair Unit (ACRU) in Sheep.

131. Study of the Articular Cartilage Repair Unit (ACRU) in Sheep Comparing Five Different Polymer Formulations.

132. Tibial Fixation of a Simulated Hamstring Anterior Cruciate Ligament Allografted in the Ovine Model.

133. Comparative Evaluation of the Osteoglass and Bioglass Putty vs. OsteoSet in Osseous Defects in the Long Bones of Goats.

134. Six-Week, Twelve-Week, Six-Month Evaluation of the Safety and efficiency of the RTI Allograft Interference Screw for Graft Fixation in ACL Reconstruction in the Ovine Model.

135. Determination of the Effects of Radiofrequency Energy Delivered on the Porcine Urethral Sphincter, Bladder Neck, Vagina, and Pelvic Floor.

136. In Vitro Evaluation of a New Linvatec RF Probe.

137. Determination of the Effects of Radiofrequency Energy Delivered on the Porcine Urethral Sphincter, Bladder Beck, Vagina, and Pelvic floor.

138. Extracoporeal Tratment of Sepsis (ECC): Animal Trials for Device Safety and Efficacy.

139. A Histological and Biomechanical Analysis of the Comparative Rate of Biological Incorporation of Biocleanse Treated Bovine bone, Untreated Bovine Bone, and Untreated Allograft Bone in the Sheep Model.

140. Comparative Healing Study of the Mitek BioComposite screw and a Mitek Absolute Bio-Interference Screw for Graft Fixation in ACL reconstruction in the Ovine Model.

141. Animal Model to Reproduce the Clinical Events in the Inter-Op Acetabular Component in Sheep.

142. A Study to Determine the Tissue Response of an injection of Gamma Sterilized Mineral Oil in the Paravertebral Muscle, the Intra-articular Space, and the Cancellous Bone of the Femoral Condyle in Rabbits.

143. Cyclically Loaded Fatigue Testing of the Mitek Cross pin and the Stryker Cross-Screw in Porcine Femur.

144. A Comparative Healing Study of the BioComposite Biosteon Screw and an Stryker Bio Screw for Graft Fixation in ACL Reconstruction in the Ovine Model.

145. Comparative Initial Fixation Strength of the Stryker Biosteon Cross Pin and the Arthrex Bio-TransFix Cross Pin by Static Fixation Testing in Porcine Femur.

146. A Study to Determine the Biomedical Strength and Histological Evidence of Healing Utilizing the Intrafix Fixation Device for Bone Tendon Fixation in the Repair of the Anterior Cruciate Ligament of Sheep.

147. A Pilot Study to Evaluate the physical ability of a sheep to recover post-operatively from bilateral ACL surgery using grafts taken from the tendon of the long digital extensor, or medial digital extensor, or lateral digital extensor.

148. A Pilot Study to Evaluate the physical ability of a sheep to recover post-operatively from bilateral ACL surgery using patellar tendon and tibial bone plug grafts.

149. A Pilot Study to Evaluate the Biological Performance & Mechanical Stability of a Partial Demineralized Anterior Longitudinal Ligament (ALL) that has been Treated with Biocleanse prior to or after the Demineralization Process then Imprinted into the Cervical Vertebra of a Sheep.

150. A Pilot Study to Evaluate the rate of Bio-Incorporation of a Porous Ceramic Body treated with an Osteo-Inductive Agent implanted into the femoral condyle of sheep.

153. An Investigation of the Histological Effects of Sustained Application of Cold at 35, 40, and 45 Degrees Farenheight on the Axial Soft Tissue in Common Swine.

154. Hybridoma Development of BALB with mice.

155. Autograph Bone Chips Plus Red Bone Marrow in the Bone Implant Interface of Porous-Coated Knee Implants.

156. Articular Carilage Defect Study in Sheep.

157. Analysis of the Initial Fixation Strength of the Stryker Biosteon Interference Screw in Porcine Femur.

158. An Investigation of the Histologic Effects of the Application of Sustained Cold at 35F and 50F on the Axial Soft Tissues in Common Swine with Sham Surgical Incisions.

159. A Three Month, Six Month, and Twelve Month Histopathological Analysis of the Comparative Rate of Biological Incorporation of OPLA Scaffold, HY-Infused OPLA Scaffold, and Empty Control Tunnels.

160. A Three Month, Six Month, and Twelve Month, and Twenty-Four Month Histopathological Analysis of the healing of Micro-Cellular Interference Screws for ACL Reconstruction.

161. A Comparative Pilot Study focusing on Adhesion Prevention Within the Suprapatellar Pouch of the Knee in the Ovine Model.

162. A Comparative Healing study in ACL Reconstruction in the Ovine Model.

163. A Comparative Study of ACL Reconstruction in the Sheep Model.

164. Radiofrequency Energy Generator Temperature and Equivalency Study.

165. A Study to Evaluate Biomet porous Ceramic block compared to Vitoss in the repair of a surgically created 10mm defect in the radial bone of Rabbits.

166. A Pilot Study to Determine the Tissue Response of an Injection of Tri-Calcium Phosphate solution in the Intra-articular Space of the Knee in Rabbits.

167. A Comparative Healing Study in ACL Reconstruction in the Ovine Model.

168. A Pilot Study to Evaluate the Short-Term Biological Performance and Mechanical Stability of the LifeCell Xenoderm Articular Repair Device in the Femoral Condyle of the Yucatan Pig.

169. A Three Month, Six Month, and Twelve Month Histopathological Analysis of the Composite Arthrex SutureTak.

170. A Comparative Study of the Mitek Biocryl Rapide Interference Screw and the Mitek Biocryl Interference Screw for Graft Fixation in ACL Reconstruction in the Ovine Model.

171. A Pilot Study of ACL Reconstruction in the Sheep Model Comparing Biocleanse Treated Grafts to Biocleanse RT Treated Grafts.

172. A Pilot Study to Evaluate the Short-Term Biological Performance and Mechanical Stability of the LifeCell Xenoderm Articular Repair Device in the Femoral Condyle of the Yucatan Pig.

173. A Pilot Study To Test An Internal Long Term Prosthetic Device In The Thoracic Extremity Of The Ovine.

174. A Pilot Study to Evaluate The Short-Term Biological Performance and Mechanical Stability of LifeCell Xenoderm Sheet Used as an ACL Replacement.

175. A Study to Evaluate Calcigen S and Calcigen S Plus Antibiotics in a Surgically Created Window in the Distal Tibia of Rabbits.